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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,056	01/11/2001	Diane Pennica	GENENT.2827A2	1938

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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/759,056

Applicant(s)
Pennica et al

Examiner
Michael Borin

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 6, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above, claim(s) 5, 6, 12-14, 17, and 22-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7-11, 15, 16, and 18-21 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachments:

- | | |
|--|---|
| 1. Notice of References Cited: PTO 892 | 4. Interview Summary: PTO 413, Paper No. s |
| 2. Notice of Draftsperson's Patent Drawing Review: PTO 948 | 5. Notice of Informal Patent Application: PTO 152 |
| 3. Information on how to obtain a copy of the PTO's report on the examination of the application | |

Art Unit: 1631

DETAILED ACTION

Status of Claims

1. Claims 1-95 are pending. It is noted that applicant seems to treat claims 5,6,12-14, 22-95 as canceled; however, no request to cancel said claims was submitted. The claims are treated as being still withdrawn from consideration. Cancellation of claims 5,6,12-14, 22-95 is requested.

Claims 1-4, 7-11, 15,16, 18-21 are under consideration.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement filed 05/06/2003 has been received and entered into the application.

The information disclosure statement contains 229 references. Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why this English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is and applicant is aware that one or more is highly relevant to patentability. M.P.E.P.

Art Unit: 1631

§ 609. This statement is in accord with *dicta* from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), which states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888. A cursory glance at the M.P.E.P. also provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974); [*Molins*]."

MPEP 2004. Therefore it is recommended that if any information that has been cited by Applicants in the information disclosure statement, is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Specification

Art Unit: 1631

Claim Rejections - 35 USC § 112, second paragraph.

4. Rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of amendment to the claims.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Rejection of claims 1,7,15,16,18-21 under 35 U.S.C. 112, first paragraph (written description) is maintained for the reasons of record.

Applicant's arguments have been fully considered but were not deemed persuasive for the following reasons.

The analysis provided by the applicant is based on Example 11 of the training materials. However, said example addresses claims drawn to isolated DNA that example are not drawn to polynucleotides having certain degree of identity with polynucleotides encoding the protein, which is the subject of the present rejection. As

Art Unit: 1631

was stated in the rejection, the polynucleotide SEQ ID No. 1 (i.e., isolated DNA that encodes protein X) itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, Examiner maintains that the claims as drawn to nucleotide sequences having more than 80% identity to said polynucleotide do not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. The claims are not drawn to polynucleotides encoding a particular protein; rather the claims are drawn to a genus of polynucleotides having more than 80% identity to polynucleotide SEQ ID No. 1. The only species specifically disclosed (i.e., SEQ ID No. 1 itself) is not representative of the genus because the genus is highly variant. Adequate written description requires more than a mere statement. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be useful in the detection of cancer are present in the specification. Examiner maintains that the specification provides insufficient written description to support the genus encompassed by the claims.

6. Enablement rejection of claims 1,7,9,15,16,18-21 under 35 U.S.C. 112 first

Art Unit: 1631

encoding just one Stra 6 polypeptide¹, so other Stra6 peptides is not an issue any longer.

Claim Rejections - 35 USC § 102.

7. Rejection of claims 1,7, 9-11 are rejected under 35 U.S.C. 102(a) as being anticipated by the sequence of Database GenEmbl, accession number AF062476 is maintained for the reasons of record and in view of the following.

Applicant argues that the provided alignment results indicate "% similarity", rather than "% identity" used in the claims. The referenced sequence has 82.59% of nucleotides that are identical with nucleotides in a nucleic acid sequence encoding protein SEQ ID No. 2, i.e., it satisfies the definition of "% identity" defined on p. 33 of specification (it is noted that pages 28-30 referred to by applicants describing % identity of nucleic acids do not contain the intended information).

In regard to claims 9-11, first, as the referenced sequence has continuous stretches matching the claimed polynucleotide, it will hybridize, as claimed, to nucleic acid encoding residues 1-667 of protein SEQ ID No. 2. Second, the claims do not on

Except for the embodiment of the claims drawn to polynucleotides having certain % similarity which might be a subject of further enablement rejection.

Art Unit: 1631

polynucleotides encoding any particular modified protein; rather, the claims read on any PRO10282 protein or derivatives thereof.

8. Rejection of claims 9-11 under 35 U.S.C. 102(a) as being anticipated by the sequence of Database GenEmbl, accession number AAV84436 is maintained for the reasons of record and in view of the following.

Applicant misread the alignment provided with the previous Office Action. The alignment covers nucleotides 1768-2663, not 1768-2049 as erroneously indicated by applicant. Thus, the reference reads on the invention as claimed.

Conclusion.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not shortened statutory period will expire on the date the advisory action is mailed, and

Art Unit: 1631

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 21, 2003

mlb



MICHAEL BORIN, PH.D.
PRIMARY EXAMINER